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PFIZER INC., PHARMACIA CORPORATION,  
AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX  
MARKETING, SALES PRACTICES AND  
PRODUCTS LIABILITY LITIGATION

*This document relates to*

LYLE MCNEAL and ROBEN TRUDO,  
Plaintiffs,

vs.

PFIZER, INC., PHARMACIA CORPORATION,  
G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.),  
and MONSANTO COMPANY,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:07-cv-5915-CRB

) **PFIZER INC., PHARMACIA**  
) **CORPORATION, AND G.D.**  
) **SEARLE LLC'S ANSWER TO**  
) **COMPLAINT**

) **JURY DEMAND ENDORSED**  
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as  
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (formerly known as "Monsanto Company"<sup>1</sup>)  
3 ("Pharmacia"), and G.D. Searle LLC ("Searle"), (collectively "Defendants") and file their  
4 Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as  
5 follows:

6 **I.**

7 **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used  
9 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted  
10 generally. Defendants may seek leave to amend this Answer when discovery reveals the  
11 specific time periods in which Plaintiffs were prescribed and used Celebrex®.

12 **II.**

13 **ANSWER**

14 **Response to Allegations Regarding Parties**

15 1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but  
16 deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain  
17 periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United  
18 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
19 accordance with their approval by the FDA. Defendants admit that, during certain periods of  
20 time, Celebrex® were manufactured and packaged for Searle, which developed, tested,  
21 marketed, co-promoted, and distributed Celebrex® in the United States to be prescribed by  
22 healthcare providers who are by law authorized to prescribe drugs in accordance with their  
23 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used

24 \_\_\_\_\_  
25 <sup>1</sup> Plaintiffs' Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity  
26 known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31,  
27 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company,  
28 Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag  
Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the  
agricultural business and does not and has not ever designed, produced, manufactured, sold, resold, or distributed  
Celebrex®. Given that Plaintiffs allege in their Complaint that Monsanto Company was involved in distributing  
Celebrex®, see PLAINTIFFS' COMPLAINT at ¶ 6, Defendants assume Plaintiffs mean to refer to 1933 Monsanto. As  
a result, Pharmacia will respond to the allegations directed at Monsanto Company.

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1 in accordance with its FDA-approved prescribing information. Defendants state that the  
2 potential effects of Celebrex® were and are adequately described in its FDA-approved  
3 prescribing information, which was at all times adequate and comported with applicable  
4 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused  
5 Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the  
6 Complaint.

7 2. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,  
9 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.  
10 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
11 damages, and deny the remaining allegations in this paragraph of the Complaint.

12 3. Defendants are without knowledge or information sufficient to form a belief as to the  
13 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,  
14 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.  
15 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
16 damages, and deny the remaining allegations in this paragraph of the Complaint.

17 4. Defendants admit that Pfizer is a Delaware corporation with its principal place of  
18 business in New York. Defendants admit that, as the result of a merger in April 2003,  
19 Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph  
20 of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants  
21 are without knowledge or information sufficient to form a belief as to the truth of such  
22 allegations, and, therefore, deny the same. Defendants admit that, during certain periods of  
23 time, Pfizer marketed and co-promoted Celebrex® in the United States, including California, to  
24 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
25 accordance with their approval by the FDA. Defendants deny the remaining allegations in this  
26 paragraph of the Complaint.

27 5. Defendants admit that Searle is a Delaware limited liability company with its principal  
28 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,

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1 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.  
2 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
3 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
4 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
5 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
6 the remaining allegations in this paragraph of the Complaint.

7 6. Defendants admit that in 1933 an entity known as Monsanto Company (“1933  
8 Monsanto”) was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of  
9 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name  
10 to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company,  
11 was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company  
12 changed its name to Monsanto Company (“2000 Monsanto”). The 2000 Monsanto is engaged  
13 in the agricultural business and does not and has not ever manufactured, marketed, sold, or  
14 distributed Celebrex®. The 2000 Monsanto is not and has never been the parent of either  
15 Searle or Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed,  
16 sold, or distributed Celebrex®, Defendants therefore state that the 2000 Monsanto is not a  
17 proper party in this matter. Defendants deny the remaining allegations in this paragraph of the  
18 Complaint. Defendants state that the response to this paragraph of the Complaint regarding  
19 Monsanto is incorporated by reference into Defendants’ responses to each and every paragraph  
20 of the Complaint referring to Monsanto and/or Defendants.

21 7. Defendants admit that Pharmacia is a Delaware corporation with its principal place of  
22 business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as  
23 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.  
24 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted  
25 Celebrex® in the United States, including California, to be prescribed by healthcare providers  
26 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
27 Defendants deny the remaining allegations in this paragraph of the Complaint.

28

**Response to Allegations Regarding Jurisdiction and Venue**

8. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny that the same. However, Defendants admit that Plaintiffs claim that the amount in controversy exceeds \$75,000, exclusive of interests and costs.

9. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of interests and costs.

10. Defendants are without knowledge or information to form a belief as to the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny committing a tort in the States of California, Missouri, and Montana, and deny the remaining allegations in this paragraph of the Complaint.

11. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Pfizer, Pharmacia, and Searle are registered to and do business in the State of and California. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny committing a tort in the States of California, Missouri, and

Montana, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Allegations Regarding Interdistrict Assignment**

12. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac. and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

**Response to Factual Allegations**

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with

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1 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
2 remaining allegations in this paragraph of the Complaint.

3 16. Defendants state that the allegations in this paragraph of the Complaint regarding  
4 aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no  
5 response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times,  
6 referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants deny the  
7 remaining allegations in this paragraph of the Complaint.

8 17. Defendants state that the allegations in this paragraph of the Complaint are not directed  
9 towards Defendants and, therefore, no response is required. To the extent that a response is  
10 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
11 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
12 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

13 18. Defendants state that the allegations in this paragraph of the Complaint are not directed  
14 towards Defendants and, therefore, no response is required. To the extent that a response is  
15 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
16 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
17 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

18 19. Defendants state that the allegations in this paragraph of the Complaint are not directed  
19 towards Defendants and, therefore, no response is required. To the extent that a response is  
20 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
21 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
22 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

23 20. Defendants state that the allegations in this paragraph of the Complaint are not directed  
24 towards Defendants and, therefore, no response is required. To the extent that a response is  
25 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
26 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
27 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

28 21. Defendants state that the allegations in this paragraph of the Complaint regarding “other

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1 pharmaceutical companies” are not directed towards Defendants and, therefore, no response is  
2 required. To the extent a response is deemed required, Defendants state that, as stated in the  
3 FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to  
4 be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2  
5 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the  
6 cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiffs fail to provide the proper context for the  
7 remaining allegations in this paragraph and Defendants therefore lack sufficient information or  
8 knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining  
9 allegations in this paragraph of the Complaint.

10 22. Defendants state that the allegations in this paragraph of the Complaint regarding  
11 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or  
12 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny  
13 the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he  
14 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,  
15 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in  
16 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants  
17 state that Celebrex® was and is safe and effective when used in accordance with its FDA-  
18 approved prescribing information. Defendants state that the potential effects of Celebrex®  
19 were and are adequately described in its FDA-approved prescribing information, which was at  
20 all times adequate and comported with applicable standards of care and law. Defendants deny  
21 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

22 23. Defendants admit that Searle submitted a New Drug Application (“NDA”) for  
23 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted  
24 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of  
25 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.  
26 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to  
27 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis  
28 (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny

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1 the remaining allegations in this paragraph of the Complaint.

2 24. Defendants admit that Celebrex® was launched in February 1999. Defendants admit  
3 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted  
4 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
5 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
6 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,  
7 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States  
8 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
9 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe  
10 and effective when used in accordance with its FDA-approved prescribing information.  
11 Defendants state that the potential effects of Celebrex® were and are adequately described in its  
12 FDA-approved prescribing information, which was at all times adequate and comported with  
13 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
14 remaining allegations in this paragraph of the Complaint.

15 25. Defendants state that the referenced article speaks for itself and respectfully refer the  
16 Court to the article for its actual language and text. Any attempt to characterize the article is  
17 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
19 this paragraph of the Complaint.

20 26. Defendants state that the referenced article speaks for itself and respectfully refer the  
21 Court to the article for its actual language and text. Any attempt to characterize the article is  
22 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
24 this paragraph of the Complaint.

25 27. Defendants state that Celebrex® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendants state that the potential effects of  
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny the allegations in this paragraph of the Complaint.

2 28. Defendants state that Celebrex® was and is safe and effective when used in accordance  
3 with its FDA-approved prescribing information. Defendants state that the potential effects of  
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
5 which was at all times adequate and comported with applicable standards of care and law.  
6 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
7 the Complaint.

8 29. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA  
9 on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to  
10 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,  
11 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself  
12 and respectfully refer the Court to the study for its actual language and text. Any attempt to  
13 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of  
14 the Complaint.

15 30. Defendants state that the referenced Medical Officer Review speaks for itself and  
16 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
17 attempt to characterize the Medical Officer Review is denied. Defendants state that the  
18 referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court  
19 to the Alert for Healthcare Professionals for its actual language and text. Any attempt to  
20 characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining  
21 allegations in this paragraph of the Complaint.

22 31. Defendants state that the referenced study speaks for itself and respectfully refer the  
23 Court to the study for its actual language and text. Any attempt to characterize the study is  
24 denied. Defendants state that the referenced article speaks for itself and respectfully refer the  
25 Court to the article for its actual language and text. Any attempt to characterize the article is  
26 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
27 paragraph of the Complaint.

28 32. Defendants state that the referenced Medical Officer Review speaks for itself and

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1 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
2 attempt to characterize the Medical Officer Review is denied. Defendants state that the  
3 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
4 language and text. Any attempt to characterize the article is denied. Defendants deny the  
5 remaining allegations in this paragraph of the Complaint.

6 33. Defendants state that the referenced article speaks for itself and respectfully refer the  
7 Court to the article for its actual language and text. Any attempt to characterize the article is  
8 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
9 paragraph of the Complaint.

10 34. Defendants state that the referenced articles speak for themselves and respectfully refer  
11 the Court to the articles for their actual language and text. Any attempt to characterize the  
12 articles is denied. Defendants state that the referenced study speaks for itself and respectfully  
13 refer the Court to the study for its actual language and text. Any attempt to characterize the  
14 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

15 35. Defendants state that the referenced Medical Officer Review speaks for itself and  
16 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
17 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
18 allegations in this paragraph of the Complaint.

19 36. Plaintiffs fail to provide the proper context for the allegations concerning “Public  
20 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or  
21 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
22 Defendants deny the remaining allegations in this paragraph of the Complaint.

23 37. Defendants state that the referenced study speaks for itself and respectfully refer the  
24 Court to the study for its actual language and text. Any attempt to characterize the study is  
25 denied. Plaintiffs fail to provide the proper context for the allegations concerning “Public  
26 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or  
27 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
28 Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 38. Defendants admit that there was a clinical trial called APC. Defendants state that the  
2 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
3 language and text. Any attempt to characterize the article is denied. Defendants deny the  
4 remaining allegations in this paragraph of the Complaint.

5 39. Defendants admit that there was a clinical trial called APC. Defendants state that the  
6 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
7 language and text. Any attempt to characterize the article is denied. Defendants deny the  
8 remaining allegations in this paragraph of the Complaint.

9 40. Defendants state that the referenced Medical Officer Review speaks for itself and  
10 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
11 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
12 allegations in this paragraph of the Complaint.

13 41. Defendants state that the referenced FDA Class Review speaks for itself and  
14 respectfully refer the Court to the CLASS Review for its actual language and text. Any attempt  
15 to characterize the CLASS Review is denied. Defendants deny the remaining allegations in this  
16 paragraph of the Complaint.

17 42. Defendants admit that there was a clinical trial called PreSAP. Plaintiffs fail to provide  
18 the proper context for the allegations concerning “other Celebrex trials” contained in this  
19 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
20 form a belief as to the truth of such allegations and, therefore, deny the same. As for the  
21 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state  
22 that the referenced study speaks for itself and respectfully refer the Court to the study for its  
23 actual language and text. Any attempt to characterize the study is denied. Defendants deny the  
24 remaining allegations in this paragraph of the Complaint.

25 43. Defendants state that the referenced article speaks for itself and respectfully refer the  
26 Court to the article for its actual language and text. Any attempt to characterize the article is  
27 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

28 44. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the

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1 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants  
2 therefore lack sufficient information or knowledge to form a belief as to the truth of such  
3 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for  
4 themselves and respectfully refer the Court to the studies for their actual language and text.  
5 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in  
6 this paragraph of the Complaint.

7 45. Defendants state that the referenced Medical Officer Review speaks for itself and  
8 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
9 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
10 allegations in this paragraph of the Complaint.

11 46. Defendants state that allegations in this paragraph of the Complaint regarding Vioxx®  
12 in this paragraph of the Complaint are not directed toward Defendants, and therefore no  
13 response is required. To the extent that a response is deemed required, Plaintiffs fail to provide  
14 the proper context for the allegations in this paragraph of the Complaint regarding Vioxx® in  
15 this paragraph of the Complaint. Defendants therefore lack sufficient information or  
16 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
17 Defendants state that the referenced study speaks for itself and respectfully refer the Court to  
18 the study for its actual language and text. Any attempt to characterize the study is denied.  
19 Defendants deny the remaining allegations in this paragraph of the Complaint.

20 47. Defendants state that allegations in this paragraph of the Complaint regarding Merck  
21 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and  
22 therefore no response is required. To the extent that a response is deemed required, Plaintiffs  
23 fail to provide the proper context for the allegations in this paragraph of the Complaint  
24 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack  
25 sufficient information or knowledge to form a belief as to the truth of such allegations and,  
26 therefore, deny the same. Defendants state that the referenced study speaks for itself and  
27 respectfully refer the Court to the study for its actual language and text. Any attempt to  
28 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of

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1 the Complaint.

2 48. Defendants state that allegations in this paragraph of the Complaint regarding Merck  
3 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and  
4 therefore no response is required. To the extent that a response is deemed required, Plaintiffs  
5 fail to provide the proper context for the allegations in this paragraph of the Complaint  
6 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack  
7 sufficient information or knowledge to form a belief as to the truth of such allegations and,  
8 therefore, deny the same. Defendants state that the referenced study speaks for itself and  
9 respectfully refer the Court to the study for its actual language and text. Any attempt to  
10 characterize the study is denied. Defendants state that the referenced article speaks for itself  
11 and respectfully refer the Court to the article for its actual language and text. Any attempt to  
12 characterize the article is denied. Defendants deny the remaining allegations in this paragraph  
13 of the Complaint.

14 49. Defendants state that Celebrex® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants deny the allegations in this  
16 paragraph of the Complaint.

17 50. Defendants state that the referenced article speaks for itself and respectfully refer the  
18 Court to the article for its actual language and text. Any attempt to characterize the article is  
19 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 51. Defendants state that allegations in this paragraph of the Complaint are not directed  
21 toward Defendants, and therefore no response is required. To the extent that a response is  
22 deemed required, Defendants state that the referenced article speaks for itself and respectfully  
23 refer the Court to the article for its actual language and text. Any attempt to characterize the  
24 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 52. Defendants deny the allegations in this paragraph of the Complaint.

26 53. Defendants state that Celebrex® was and is safe and effective when used in accordance  
27 with its FDA-approved prescribing information. Defendants state that the potential effects of  
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.  
2 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
3 remaining allegations contained in this paragraph of the Complaint.

4 54. Defendants deny any wrongful conduct and deny the allegations contained in this  
5 paragraph of the Complaint.

6 55. Defendants deny any wrongful conduct and deny the allegations contained in this  
7 paragraph of the Complaint.

8 56. Defendants state that Celebrex® was and is safe and effective when used in accordance  
9 with its FDA-approved prescribing information. Defendants state that the potential effects of  
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
11 which was at all times adequate and comported with applicable standards of care and law.  
12 Defendants deny any wrongful conduct and deny the remaining allegations contained in this  
13 paragraph of the Complaint.

14 57. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
16 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
17 effective when used in accordance with its FDA-approved prescribing information. Defendants  
18 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
19 approved prescribing information, which was at all times adequate and comported with  
20 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
21 Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of  
22 the Complaint.

23 58. Defendants admit that the FDA Division of Drug Marketing, Advertising, and  
24 Communications (“DDMAC”) sent a letter to Pfizer dated January 10, 2005. Defendants state  
25 that the referenced letter speaks for itself and respectfully refer the Court to the letter for its  
26 actual language and text. Any attempt to characterize the letter is denied. Defendants admit  
27 that the DDMAC sent a letter to Searle dated October 6, 1999. Defendants state that the  
28 referenced letter speaks for itself and respectfully refer the Court to the letter for its actual

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1 language and text. Any attempt to characterize the letter is denied. Defendants state that the  
2 transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and  
3 respectfully refer the Court to the transcripts for their actual language and text. Any attempt to  
4 characterize the transcripts is denied. Defendants state that the referenced study speaks for  
5 itself and respectfully refer the Court to the article for its actual language and text. Any attempt  
6 to characterize the article is denied. Defendants deny the remaining allegations in this  
7 paragraph of the Complaint.

8 59. Defendants state that Celebrex® was and is safe and effective when used in accordance  
9 with its FDA-approved prescribing information. Defendants state that the potential effects of  
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
11 which was at all times adequate and comported with applicable standards of care and law.  
12 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
13 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
14 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
15 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
16 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
17 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
18 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
19 allegations in this paragraph of the Complaint.

20 60. Defendants state that Celebrex® was and is safe and effective when used in accordance  
21 with its FDA-approved prescribing information. Defendants state that the potential effects of  
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
23 which was at all times adequate and comported with applicable standards of care and law.  
24 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
25 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
26 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
27 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
28 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the

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United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

61. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that Plaintiffs' allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the allegations in this paragraph of the Complaint.

62. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for

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1 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
2 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
3 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
4 allegations in this paragraph of the Complaint.

5 63. Defendants state that Celebrex® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
8 which at all times was adequate and comported with applicable standards of care and law.  
9 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
10 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
11 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
12 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
13 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
14 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
15 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
16 allegations in this paragraph of the Complaint.

17 64. Defendants state that Celebrex® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendants state that the potential effects of  
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
20 which was at all times adequate and comported with applicable standards of care and law.  
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
22 the Complaint.

23 65. Defendants state that Celebrex® was and is safe and effective when used in accordance  
24 with its FDA-approved prescribing information. Defendants state that the potential effects of  
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
26 which was at all times adequate and comported with applicable standards of care and law.  
27 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
28 the Complaint.

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66. Defendants deny the allegations in this paragraph of the Complaint.

67. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

68. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

69. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

70. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

71. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
2 the Complaint.

3 72. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® are and were adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants state that the referenced study speaks for itself and respectfully refer the Court to  
8 the study for its actual language and text. Any attempt to characterize the study is denied.  
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
10 the Complaint.

11 73. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
13 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
14 effective when used in accordance with its FDA-approved prescribing information. Defendants  
15 state that the potential effects of Celebrex® are and were adequately described in its FDA-  
16 approved prescribing information, which was at all times adequate and comported with  
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
18 remaining allegations in this paragraph of the Complaint.

19 **Response to First Cause of Action: Negligence**

20 74. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
21 Complaint as if fully set forth herein.

22 75. Defendants state that this paragraph of the Complaint contains legal contentions to  
23 which no response is required. To the extent that a response is deemed required, Defendants  
24 admit that they had duties as are imposed by law but deny having breached such duties.  
25 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
26 FDA-approved prescribing information. Defendants state that the potential effects of  
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
2 the Complaint.

3 76. Defendants state that this paragraph of the Complaint contains legal contentions to  
4 which no response is required. To the extent that a response is deemed required, Defendants  
5 admit that they had duties as are imposed by law but deny having breached such duties.  
6 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
7 FDA-approved prescribing information. Defendants state that the potential effects of  
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
9 which was at all times adequate and comported with applicable standards of care and law.  
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
11 the Complaint.

12 77. Defendants are without knowledge or information sufficient to form a belief as to the  
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
14 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
15 effective when used in accordance with its FDA-approved prescribing information. Defendants  
16 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
17 approved prescribing information, which was at all times adequate and comported with  
18 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
19 remaining allegations in this paragraph of the Complaint, including all subparts.

20 78. Plaintiffs' Complaint omits Paragraph 78.

21 79. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
23 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
24 effective when used in accordance with its FDA-approved prescribing information. Defendants  
25 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
26 approved prescribing information, which was at all times adequate and comported with  
27 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
28 remaining allegations in this paragraph of the Complaint.

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1 80. Defendants state that Celebrex® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
6 the Complaint.

7 81. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
9 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
10 effective when used in accordance with its FDA-approved prescribing information. Defendants  
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
12 approved prescribing information, which was at all times adequate and comported with  
13 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
14 Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations in this  
15 paragraph of the Complaint.

16 82. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
18 Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that  
19 Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations in this  
20 paragraph of the Complaint.

21 83. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
22 damages, and deny the remaining allegations in this paragraph of the Complaint.

23 84. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
24 damages, and deny the remaining allegations in this paragraph of the Complaint.

25 **Response to Second Cause of Action: Strict Liability**

26 85. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
27 Complaint as if fully set forth herein.

28 86. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
2 Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of  
3 time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be  
4 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
5 with their approval by the FDA. Defendants admit that, during certain periods of time,  
6 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-  
7 promoted and distributed Celebrex® in the United States to be prescribed by healthcare  
8 providers who are by law authorized to prescribe drugs in accordance with their approval by the  
9 FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and  
10 consumers without substantial change from the time of sale. Defendants deny the remaining  
11 allegations in this paragraph of the Complaint.

12 87. Defendants state that Celebrex® was and is safe and effective when used in accordance  
13 with its FDA-approved prescribing information. Defendants state that the potential effects of  
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
15 which was at all times adequate and comported with applicable standards of care and law.  
16 Defendants deny the remaining allegations in this paragraph of the Complaint.

17 88. Defendants state that Celebrex® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendants state that the potential effects of  
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
20 which was at all times adequate and comported with applicable standards of care and law.  
21 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the  
22 remaining allegations in this paragraph of the Complaint.

23 89. Defendants state that Celebrex® was and is safe and effective when used in accordance  
24 with its FDA-approved prescribing information. Defendants state that the potential effects of  
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
26 which was at all times adequate and comported with applicable standards of care and law.  
27 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the  
28 remaining allegations in this paragraph of the Complaint, including all subparts.

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1 90. Defendants state that Celebrex® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants deny that Celebrex® is unreasonably dangerous and deny the remaining allegations  
6 in this paragraph of the Complaint.

7 91. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
9 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
10 effective when used in accordance with its FDA-approved prescribing information. Defendants  
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
12 approved prescribing information, which was at all times adequate and comported with  
13 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
14 Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damages, and deny the  
15 remaining allegations in this paragraph of the Complaint.

16 92. Defendants state that Celebrex® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
21 remaining allegations in this paragraph of the Complaint.

22 93. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
24 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
25 effective when used in accordance with its FDA-approved prescribing information. Defendants  
26 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
27 approved prescribing information, which was at all times adequate and comported with  
28 applicable standards of care and law. Defendants deny any wrongful conduct, deny that

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1 Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damages, and deny the  
2 remaining allegations in this paragraph of the Complaint.

3 94. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
8 the Complaint.

9 95. Defendants are without knowledge or information sufficient to form a belief as to the  
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
11 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
12 effective when used in accordance with its FDA-approved prescribing information. Defendants  
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
14 approved prescribing information, which was at all times adequate and comported with  
15 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
16 Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations in this  
17 paragraph of the Complaint.

18 96. Defendants state that Celebrex® was and is safe and effective when used in accordance  
19 with its FDA-approved prescribing information. Defendants state that the potential effects of  
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
21 which was at all times adequate and comported with applicable standards of care and law.  
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
23 the Complaint.

24 97. Defendants are without knowledge or information sufficient to form a belief as to the  
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
26 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
27 effective when used in accordance with its FDA-approved prescribing information. Defendants  
28 state that the potential effects of Celebrex® were and are adequately described in its FDA-

1 approved prescribing information, which was at all times adequate and comported with  
2 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
3 remaining allegations in this paragraph of the Complaint.

4 98. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
5 damages, and deny the remaining allegations in this paragraph of the Complaint.

6 99. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
7 damages, and deny the remaining allegations in this paragraph of the Complaint.

8 100. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
9 damages, and deny the remaining allegations in this paragraph of the Complaint.

10 **Response to Third Cause of Action: Breach of Express Warranty**

11 101. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
12 Complaint as if fully set forth herein.

13 102. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
15 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
16 effective when used in accordance with its FDA-approved prescribing information. Defendants  
17 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
18 approved prescribing information, which was at all times adequate and comported with  
19 applicable standards of care and law. Defendants admit that they provided FDA-approved  
20 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in  
21 this paragraph of the Complaint.

22 103. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
24 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
25 effective when used in accordance with its FDA-approved prescribing information. Defendants  
26 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
27 approved prescribing information, which was at all times adequate and comported with  
28 applicable standards of care and law. Defendants admit that they provided FDA-approved

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1 prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and  
2 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

3 104. Defendants admit that they provided FDA-approved prescribing information regarding  
4 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this  
5 paragraph of the Complaint.

6 105. Defendants state that Celebrex® was and is safe and effective when used in accordance  
7 with its FDA-approved prescribing information. Defendants state that the potential effects of  
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
9 which was at all times adequate and comported with applicable standards of care and law.  
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
11 the Complaint.

12 106. Defendants state that Celebrex® was and is safe and effective when used in accordance  
13 with its FDA-approved prescribing information. Defendants state that the potential effects of  
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
15 which was at all times adequate and comported with applicable standards of care and law.  
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
17 the Complaint.

18 107. Defendants are without knowledge or information sufficient to form a belief as to the  
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
20 Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of  
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
22 which was at all times adequate and comported with applicable standards of care and law.  
23 Defendants admit that they provided FDA-approved prescribing information regarding  
24 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 108. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
26 damages, and deny the remaining allegations in this paragraph of the Complaint.

27 109. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
28 damages, and deny the remaining allegations in this paragraph of the Complaint.

1 110. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
2 damages, and deny the remaining allegations in this paragraph of the Complaint.

3 **Response to Fourth Cause of Action: Breach of Implied Warranty**

4 111. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
5 Complaint as if fully set forth herein.

6 112. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
7 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
8 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
9 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
10 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
11 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
12 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
13 the remaining allegations in this paragraph of the Complaint.

14 113. Defendants state that Celebrex® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants state that the potential effects of  
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
17 which was at all times adequate and comported with applicable standards of care and law.  
18 Defendants admit that they provided FDA-approved prescribing information regarding  
19 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 114. Defendants state that Celebrex® was and is safe and effective when used in accordance  
21 with its FDA-approved prescribing information. Defendants state that the potential effects of  
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
23 which was at all times adequate and comported with applicable standards of care and law.  
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 115. Defendants are without knowledge or information sufficient to form a belief as to the  
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
27 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
2 approved prescribing information, which was at all times adequate and comported with  
3 applicable standards of care and law. Defendants admit that they provided FDA-approved  
4 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in  
5 this paragraph of the Complaint.

6 116. Defendants are without knowledge or information sufficient to form a belief as to the  
7 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
8 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,  
9 Celebrex® was expected to reach users and consumers without substantial change from the  
10 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 117. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
13 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
14 effective when used in accordance with its FDA-approved prescribing information. Defendants  
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
16 approved prescribing information, which was at all times adequate and comported with  
17 applicable standards of care and law. Defendants deny any wrongful conduct, deny that they  
18 breached any warranty, and deny the remaining allegations in this paragraph of the Complaint.

19 118. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
20 damages, and deny the remaining allegations in this paragraph of the Complaint.

21 119. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
22 damages, and deny the remaining allegations in this paragraph of the Complaint.

23 120. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
24 damages, and deny the remaining allegations in this paragraph of the Complaint.

25 **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

26 121. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
27 Complaint as if fully set forth herein.

28 122. Defendants state that this paragraph of the Complaint contains legal contentions to

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1 which no response is required. To the extent that a response is deemed required, Defendants  
2 admit that they had duties as are imposed by law but deny having breached such duties.  
3 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
4 FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
8 the Complaint.

9 123. Defendants state that Celebrex® was and is safe and effective when used in accordance  
10 with its FDA-approved prescribing information. Defendants state that the potential effects of  
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
12 which was at all times adequate and comported with applicable standards of care and law.  
13 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
14 the Complaint, including all subparts.

15 124. Defendants state that Celebrex® was and is safe and effective when used in accordance  
16 with its FDA-approved prescribing information. Defendants state that the potential effects of  
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
18 which was at all times adequate and comported with applicable standards of care and law.  
19 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
20 the Complaint.

21 125. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
23 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
24 effective when used in accordance with its FDA-approved prescribing information. Defendants  
25 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
26 approved prescribing information, which was at all times adequate and comported with  
27 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
28 Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this

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1 paragraph of the Complaint.

2 126. Defendants state that Celebrex® was and is safe and effective when used in accordance  
3 with its FDA-approved prescribing information. Defendants state that the potential effects of  
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
5 which was at all times adequate and comported with applicable standards of care and law.  
6 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
7 the Complaint.

8 127. Defendants are without knowledge or information sufficient to form a belief as to the  
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
10 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
11 effective when used in accordance with its FDA-approved prescribing information. Defendants  
12 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
13 approved prescribing information, which was at all times adequate and comported with  
14 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
15 remaining allegations in this paragraph of the Complaint.

16 128. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
18 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
19 effective when used in accordance with its FDA-approved prescribing information. Defendants  
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
21 approved prescribing information, which was at all times adequate and comported with  
22 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
23 remaining allegations in this paragraph of the Complaint.

24 129. Defendants are without knowledge or information sufficient to form a belief as to the  
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
26 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
27 effective when used in accordance with its FDA-approved prescribing information. Defendants  
28 state that the potential effects of Celebrex® were and are adequately described in its FDA-

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1 approved prescribing information, which was at all times adequate and comported with  
2 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
3 remaining allegations in this paragraph of the Complaint.

4 130. Defendants are without knowledge or information sufficient to form a belief as to the  
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
6 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
7 effective when used in accordance with its FDA-approved prescribing information. Defendants  
8 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
9 approved prescribing information, which was at all times adequate and comported with  
10 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
11 remaining allegations in this paragraph of the Complaint.

12 131. Defendants are without knowledge or information sufficient to form a belief as to the  
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
14 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
15 effective when used in accordance with its FDA-approved prescribing information. Defendants  
16 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
17 approved prescribing information, which was at all times adequate and comported with  
18 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
19 remaining allegations in this paragraph of the Complaint.

20 132. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
22 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
23 effective when used in accordance with its FDA-approved prescribing information. Defendants  
24 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
25 approved prescribing information, which was at all times adequate and comported with  
26 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
27 remaining allegations in this paragraph of the Complaint.

28 133. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or

1 damages, and deny the remaining allegations in this paragraph of the Complaint.

2 134. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
3 damages, and deny the remaining allegations in this paragraph of the Complaint.

4 135. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or  
5 damages, and deny the remaining allegations in this paragraph of the Complaint.

6 **Response to Sixth Cause of Action: Unjust Enrichment**

7 136. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
8 Complaint as if fully set forth herein.

9 137. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
10 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
11 are by law authorized to prescribe drugs in accordance with their approval by the FDA.

12 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
13 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
14 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
15 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
16 the remaining allegations in this paragraph of the Complaint.

17 138. Defendants are without knowledge or information sufficient to form a belief as to the  
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
19 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this  
20 paragraph of the Complaint.

21 139. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
23 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this  
24 paragraph of the Complaint.

25 140. Defendants are without knowledge or information sufficient to form a belief as to the  
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used  
27 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

141. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

142. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

#### **Response to Prayer for Relief**

Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations in paragraph of the Complaint headed “Prayer for Relief,” including all subparts.

### **III.**

#### **GENERAL DENIAL**

Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs’ Complaint that have not been previously admitted, denied, or explained.

### **IV.**

#### **AFFIRMATIVE DEFENSES**

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

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**First Defense**

1. The Complaint fails to state a claim upon which relief can be granted.

**Second Defense**

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

**Third Defense**

3. At all relevant times, Defendants provided proper warnings, information, and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

**Fourth Defense**

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed, and distributed.

**Fifth Defense**

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pleaded in full bar of any liability as to Defendants.

**Sixth Defense**

6. Plaintiffs' action is barred by the statute of repose.

**Seventh Defense**

7. Plaintiffs' claims against Defendants are barred to the extent Plaintiffs were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiffs should be diminished accordingly.

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**Eighth Defense**

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

**Ninth Defense**

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

**Tenth Defense**

10. Any injuries or expenses incurred by Plaintiffs were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

**Eleventh Defense**

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs.

**Twelfth Defense**

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs’ treating and prescribing physicians.

**Thirteenth Defense**

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

**Fourteenth Defense**

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of

the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

#### **Fifteenth Defense**

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiffs was prepared in accordance with the applicable standard of care.

#### **Sixteenth Defense**

16. Plaintiffs' alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

#### **Seventeenth Defense**

17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendants.

#### **Eighteenth Defense**

18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

#### **Nineteenth Defense**

19. Plaintiffs knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

#### **Twentieth Defense**

20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

#### **Twenty-first Defense**

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**Twenty-second Defense**

22. The manufacture, distribution, and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

**Twenty-third Defense**

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

**Twenty-fourth Defense**

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

**Twenty-fifth Defense**

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

**Twenty-sixth Defense**

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

**Twenty-seventh Defense**

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

**Twenty-eighth Defense**

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

**Twenty-ninth Defense**

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

**Thirtieth Defense**

30. Defendants affirmatively aver that the imposition of punitive damages in this case would violate Defendants' rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of California, Missouri, and Montana, and would additionally violate Defendants' rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

**Thirty-first Defense**

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

**Thirty-second Defense**

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

**Thirty-third Defense**

33. Plaintiffs' punitive damage claims are preempted by federal law.

**Thirty-fourth Defense**

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

**Thirty-fifth Defense**

35. Plaintiffs failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

**Thirty-sixth Defense**

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

**Thirty-seventh Defense**

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

**Thirty-eighth Defense**

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of Missouri, Montana, and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs ; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources*,

1 *Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State*  
2 *Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

3 **Thirty-ninth Defense**

4 39. The methods, standards, and techniques utilized with respect to the manufacture, design,  
5 and marketing of Celebrex®, if any, used in this case, included adequate warnings and  
6 instructions with respect to the product's use in the package insert and other literature, and  
7 conformed to the generally recognized, reasonably available, and reliable state of the  
8 knowledge at the time the product was marketed.

9 **Fortieth Defense**

10 40. The claims asserted in the Complaint are barred because Celebrex® was designed,  
11 tested, manufactured, and labeled in accordance with the state-of-the-art industry standards  
12 existing at the time of the sale.

13 **Forty-first Defense**

14 41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon  
15 information and belief, such injuries and losses were caused by the actions of persons not  
16 having real or apparent authority to take said actions on behalf of Defendants and over whom  
17 Defendants had no control and for whom Defendants may not be held accountable.

18 **Forty-second Defense**

19 42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®  
20 was not unreasonably dangerous or defective, was suitable for the purpose for which it was  
21 intended, and was distributed with adequate and sufficient warnings.

22 **Forty-third Defense**

23 43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches,  
24 waiver, and/or estoppel.

25 **Forty-fourth Defense**

26 44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the  
27 pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases or  
28 illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were

1 independent of or far removed from Defendants' conduct.

2 **Forty-fifth Defense**

3 45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®  
4 did not proximately cause injuries or damages to Plaintiffs.

5 **Forty-sixth Defense**

6 46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs  
7 did not incur any ascertainable loss as a result of Defendants' conduct.

8 **Forty-seventh Defense**

9 47. The claims asserted in the Complaint are barred, in whole or in part, because the  
10 manufacturing, labeling, packaging, and any advertising of the product complied with the  
11 applicable codes, standards and regulations established, adopted, promulgated or approved by  
12 any applicable regulatory body, including but not limited to the United States, any state, and  
13 any agency thereof.

14 **Forty-eighth Defense**

15 48. The claims must be dismissed because Plaintiffs would have taken Celebrex® even if  
16 the product labeling contained the information that Plaintiffs contend should have been  
17 provided.

18 **Forty-ninth Defense**

19 49. The claims asserted in the Complaint are barred because the utility of Celebrex®  
20 outweighed its risks.

21 **Fiftieth Defense**

22 50. Plaintiffs' damages, if any, are barred or limited by the payments received from  
23 collateral sources.

24 **Fifty-first Defense**

25 51. Defendants' liability, if any, can only be determined after the percentages of  
26 responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if  
27 any, are determined. Defendants seek an adjudication of the percentage of fault of the  
28 claimants and each and every other person whose fault could have contributed to the alleged

1 injuries and damages, if any, of Plaintiffs .

2 **Fifty-second Defense**

3 52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the  
4 common law gives deference to discretionary actions by the United States Food and Drug  
5 Administration under the Federal Food, Drug, and Cosmetic Act.

6 **Fifty-third Defense**

7 53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®  
8 is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act  
9 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs'  
10 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the  
11 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,  
12 and with the specific determinations by FDA specifying the language that should be used in the  
13 labeling accompanying Celebrex®. Accordingly, Plaintiffs' claims are preempted by the  
14 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the  
15 United States.

16 **Fifty-fourth Defense**

17 54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity  
18 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

19 **Fifty-fifth Defense**

20 55. Defendants state on information and belief that the Complaint and each purported cause  
21 of action contained therein is barred by the statutes of limitations contained in California Code  
22 of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation  
23 as may apply.

24 **Fifty-sixth Defense**

25 56. Defendants state on information and belief that any injuries, losses, or damages suffered  
26 by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable  
27 conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery against  
28 Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

**Fifty-seventh Defense**

57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

**Fifty-eighth Defense**

58. Plaintiffs' claims are barred by the limitations and defenses set out in the Missouri Product Liability Act, Mo. Rev. Stat. § 537.760 *et seq.*, including but not limited to, the "state of the art" defenses as defined in Mo. Rev. Stat. § 537.764. Defendants incorporate by reference all defenses and/or limitations set forth or referenced in the Missouri Product Liability Act.

**Fifty-ninth Defense**

59. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants is not liable in any way. Mo. Rev. Stat. § 537.765.

**Sixtieth Defense**

60. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and Article I, § 17 of the Constitution of the State of Missouri, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

**Sixty-first Defense**

61. Plaintiffs' claims for punitive damages are subject to all provisions of Missouri law.

**Sixty-second Defense**

62. Defendants deny that they are liable for any damages in this case. Defendants contend, however, that any damage award to Plaintiffs that utilizes the Missouri joint and several liability scheme would be unconstitutional, as this scheme is violative of Defendants' due

process and equal protection guarantees under the United States and Missouri Constitutions. The Missouri joint and several liability scheme, under Mo. Rev. Stat. § 537.067, violates Defendants' due process guarantees because no legitimate state interest supports § 537.067, and, furthermore, no rational relationship exists between a legitimate state interest and the promotion of the Missouri joint and several liability scheme. Additionally, the Missouri system of assessing joint and several liability violates Defendants' equal protection guarantees because it operates to create arbitrary classifications of individuals, and to treat similarly situated individuals dissimilarly under the law. The joint and several liability scheme is also unconstitutionally void for vagueness under the United States and Missouri Constitutions. Thus, the scheme is unconstitutional and should not be applied in this action.

### **Sixty-third Defense**

63. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

**V.**

### **PRAYER**

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' alleged injuries, losses, or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiffs' injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

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June 13, 2008

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LLC

**JURY DEMAND**

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

June 13, 2008

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